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(54) A HAEMODIALYSIS MACHINE

(71) We, LUCAS INDUSTRIES LIMITED, formerly Joseph Lucas (Industries Limited of Great King Street, Birmingham, 19 a British Company do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a haemodialysis machine.

In accordance with the present invention there is provided a haemodialysis machine comprising a blood pump, a dialyser and a bubble trap downstream of the dialyser and means for detecting air bubbles in the blood leaving the bubble trap in use via a translucent or transparent tube, said bubble detecting means comprising a lamp and a photocell on opposite sides of said tube so that the intensity of light falling on the photocell from the lamp is dependent upon the opacity of the contents of said tube between the lamp and the photocell, and a switching circuit which has two states between which it is arranged to switch when the intensity of illumination of light received by the photocell deviates beyond a predetermined limit.

Preferably, said photocell is a phototransistor and said switching circuit includes a semi-conductor switching element.

The invention will now be more particularly described with reference to the accompanying drawings wherein:—

Figure 1 is a diagrammatic view of a haemodialysis machine incorporating one embodiment of the present invention, and

Figure 2 is an electric circuit diagram used in conjunction with the machine illustrated in Figure 1.

Referring more particularly to Figure 1 of the drawings there is shown therein a haemodialysis machine comprising a feed tube 10 which is formed of transparent or translucent synthetic resin material and through which blood passes from a patient undergoing treatment to a fistula sack 11, the blood then passes from the outlet of the fistula sack 11 to a blood pump 12 and thereafter the blood is passed through a dialyser 13. After the blood has passed through the dialyser it is fed into a bubble trap 14 from where it is returned to the patient through a transparent or translucent synthetic resin tube 15. A heparin inlet feed tube 16 and a saline drip 17 are connected to the feed tube 10 downstream of the fistula sack 11. The heparin is fed into of the fistula sack 11. The heparin is fed into the blood to prevent blood clotting as it is fed through the haemodialysis machine.

It is important to ensure that no air bubbles become entrapped in the blood as it is fed through the haemodialysis machine and to this end a bubble detector 18 is disposed downstream of the bubble trap 14 and a further bubble detector 19 is located on the tube 10 intermediate the saline drip 17 and the blood pump 12. The detectors 18 and 19 each include a lamp 20*a*, 20*b* respectively and a photocell, preferably in the form of a photo transistor 21*a*, 21*b* respectively. The detector 18 and the detector 19 are each mounted in a housing which can be clipped onto the tube through which liquid is flowing and these housings (not shown) are more particularly described in our co-pending Patent Application No. 10920/71 serial No. 1373813. The phototransistor 21*a* or 21*b* is arranged so that when a bubble presents itself in the blood between the lamp 20*a* or 20*b* and the phototransistor 21*a* or 21*b* respectively then the intensity of the light falling on the phototransistor 21*a* or 21*b* will increase to actuate a switching circuit which will be described hereinafter.

Figure 2 illustrates the switching circuit referred to above. This switching circuit comprises a pair of supply rails 22 and 23 wherein the supply rail 22 is maintained at +12 volts and wherein the rail 23 is maintained at earth potential. The lamp 20*b* is connected between the rail 22 and the cathode of a zener diode 24, the anode of

the zener diode 24 being connected to the rail 23. A resistor 25 is connected between the cathode of the zener diode 24 and the rail 23. The collector of the photo-transistor 21*b* is connected to the rail 22 whilst the emitter of the photo-transistor 21*b* is connected to the rail 23 via a delay circuit which comprises a resistor 26 in series with a variable resistor 27, a capacitor 28 bridging the resistors 26 and 27. The emitter of the phototransistor 21*b* is also connected to the anode of a diode 29, the cathode of which is connected to the base of an N P N transistor 30. The collector of the transistor 30 is connected to the rail 22 through a resistor 31 and to the rail 23 through a pair of series connected resistors 32 and 33 whilst the emitter of the transistor 30 is connected to the rail 23 through a resistor 32*a*.

There is also provided a logic unit 34 having fourteen terminals 34*a*, 34*b*, 34*c*, 34*d*, 34*e*, 34*f*, 34*g*, 34*h*, 34*i*, 34*j*, 34*k*, 34*l*, 34*m*, 34*n*. This logic 34 will be described more particularly hereinafter. However, the cathode of the zener diode 24 is connected to the terminal 34*a* of the logic unit 34 and it is also connected via a switch 35 to the terminal 34*m* of the logic unit 34. Moreover, the junction of the two resistors 32 and 33 is connected to the terminal 34*b* of the logic unit 34.

The lamp 20*a* is connected between the rail 22 and the cathode of zener diode 36, the anode of which is connected to the rail 23. The cathode of the zener diode 34 is connected through a resistor 37 to the rail 23 and it is also connected to the terminal 34*e* of the logic unit 34. The photo-transistor 21*a* has its collector connected to the rail 22 and its emitter connected to the rail 23 via a delay circuit which comprises a resistor 38 in series with a variable resistor 39, a capacitor 40 bridging the resistors 38 and 39. The emitter of the photo-transistor 21*a* is also connected to the anode of the diode 41, the cathode of which is connected to the base of the N P N transistor 42. The collector of the transistor 42 is connected through a resistor 43 to the rail 22 and through a pair of series connected resistors 44 and 45 to the rail 23. The emitter of the transistor 42 is connected through a resistor 46 to the rail 23. The junction of the resistors 44 and 45 is connected to the terminal 34*d* of the logic unit 34.

An N P N transistor 47 has its collector connected through a resistor 48 to the rail 22 and its emitter connected to the terminal 34*n* of the logic unit 34. The base of the transistor 47 is connected through a resistor 49 to the rail 22 and through a resistor 50 through the rail 23.

An N P N transistor 51 has its collector connected through a relay coil 52 to the rail 22 and its emitter connected to the rail 23. The base of the transistor 51 is connected through a resistor 53 to the terminal 34*h* of the logic unit 34. The relay coil 52 actuates a pair of associated contacts 54 and a movable contact 55. The pair of relay contacts 54 is connected to a warning circuit in the haemo-dialysis machine. The contacts 54 are held open by current flowing through the coil 52 and these contacts 54 are arranged so that when they close then the haemo-dialysis machine is de-energised and an alarm bell and/or warning light is energised. The contact 55 forms part of a changeover switch having two fixed contacts 55*a*, and 55*b*. The fixed contact 55*a* is connected to the rail 22 *via* a resistor 56 and the fixed contact 55*b* is connected to the rail 23 via a solenoid coil 57. The movable contact 55 is connected to the rail 23 via a capacitor 58. When the relay coil 52 is energised the movable contact 55 contacts the fixed contact 55*a* so that the capacitor charges *via* the resistor 56 and when the relay coil 52 is de-energised the movable contact 55 contacts the fixed contact 55*b* to discharge the capacitor 58 through the coil 57 which actuates a retaining pin to permit a spring loaded plunger (not shown) to pinch the tube 15 so as to thereby prevent blood which is flowing through the haemodialysis machine to return to the patient undergoing treatment.

The logic unit 34 comprises a pair of four input And gates 59 and 60, the four inputs to the first And gate 59 are taken from the terminals 34*a*, 34*b*, 34*d*, 34*e* and the output of the And gate 59 is connected to the terminal 34*f*. The four inputs of the second And gate 60 are taken from terminals 34*i*, 34*j*, 34*i*, and 34*m* and the output from the And gate 60 is connected to the terminal 34*h*. The transistor 47 together with the resistors 48, 49 and 50 arrange for a five volt stabilised supply to be fed to the And gate 60 for biasing purposes. Terminal 34*g* of the logic unit 34 is connected to earth potential and the terminal 34*f* is connected to terminals, 34*i*, 34*j*, and 34*l*. Terminals 34*c*, and 34*k* are unconnected.

In operation, it is necessary that the pair of contacts 54 are open and the contact 55 contacts the contact 55*a* unless a fault occurs in the haemodialysis machine. It is therefore necessary for a current to normally flow through the coil 52 and thus a positive voltages required at the base of the transistor 51 to hold the latter conductive. For a positive voltage to be presented to the base of the transistor 51 the And gate 60 must have a signal applied to all its four inputs. In order that this requirement is satisfied there must be an output from the And gate 59 and this will only occur when the correct input levels are applied to the four points of this And gate 59. The output

from said first mentioned And gate will be inhibited unless a predetermined voltage level is applied to each of the four inputs of that gate. The required input voltage at the terminals 34*a* and 34*e*, of the logic unit 34 will only be present if the lamps 20*b* and 20*a* are functioning properly. If either or both of the lamps 20*b* and 20*a* malfunction then the voltage presented to the associated terminal of the logic unit 32 will either decrease or if the lamps open circuit a zero voltage will be applied to these inputs. For the required input to be presented to the terminal 34*b* of the logic unit 34 the transistor 30 must be non-conductive and the transistor 30 will only be switched to a conductive state if the intensity of light falling on the photo-transistor 21*b* exceeds a predetermined value. Thus, if a bubble appears between the lamp 20*b* and the photo-transistor 21*b* the transistor 30 will be switched to the conductive state. However, bubbles not exceeding a predetermined size can be allowed to pass into the haemo-dialysis machine and the delay circuit associated with the photo-transistor 21*b* is provided for this purpose. The size of the bubble permitted to flow into the haemo-dialysis machine can be varied by adjusting the variable resistor 27.

The values of the resistors 43, 44 and 45 are so chosen that the required voltage input to the terminal 34*d* of the logic unit 34 so as to maintain an output from the And gate 59, will only be present if the transistor 42 is switched off. Thus, as in the case of the photo-transistor 20*b*, it is necessary that the intensity of light falling on the photo-transistor 21*a* is below a value which causes the transistor 42 to switch to a conductive state. The values of the parameters in the associated circuit are so arranged that whilst blood is passing between the lamp 20*a* and the photo-transistor 21*a* then the transistor 42 will be maintained in a non-conductive state. However, if a bubble presents itself between the lamp 20*a* and the photo-transistor 21*a* then the transistor 42 will switch to a conductive state to thereby inhibit the provision of an output from said first mentioned And gate. It is permissible to allow a bubble which does not exceed a predetermined size to pass back into the patient undergoing treatment and to this end the delay circuit associated with the photo-transistor 21*a* operates in a manner similar to the delay circuit associated with the photo-transisistor 21*b* which has previously been described.

The transistor 51 will be maintained in a conductive state if And gate 60 supplies an output to the base of the transistor 48. For an output to be presented by the And gate 60 it is necessary that the And gate 59 presents an output which supplies three of the inputs of the And gate 60 and it is furthermore essential that the switch 35 is closed. The switch 35 is so arranged that it opens upon actuation by the fistula sack 11, such actuation occurring if the pump 12 tries to draw blood from the patient at an excessive rate. Therefore, if the switch 35 opens, or either or both the lamps 20*b* and 20*a* malfunction, or a bubble above a predetermined size presents itself between the lamp 20*b* and the photo-transistor 21*b* or the lamp 20*a* and the photo-transistor 21*a* then the transistor 48 will switch to a non-conductive state. If and when this occurs the pair of contacts 54 will close to, therefore, de-energise the haemo-dialysis machine and provide a warning signal to the operator thereof. Furthermore, the contact 55 will change over to contact the fixed contact 55*b* and the capacitor 56 will discharge through the solenoid coil 57 to thereby cause the aforesaid plunger to grip the tube 15 to preclude any further blood from being returned to the patient undergoing treatment.

Provision may be made for backwashing of blood in the dialyser into the patient after disconnection of the tube 10 from the patient at the end of the treatment. This is preferable so as to avoid the wastage of blood and to this end it will be necessary to provide the photo-transistor 21*a* with associated circuitry which can be switched, from a state in which it detects bubbles in blood to a state in which it detects bubbles in saline.

Moreover, if desired, one or more further detectors may be incorporated in the circuit described above.

It is to be appreciated that although as has been hereinbefore described the photocells are in the form of photo-transistors, any other convenient form of photo-cell may be used together with suitable associated circuitry.

Finally, the solenoid coil 57 can be connected so that it is normally energised and have a spring loaded plunger associated therewith. Thus, when the contacts 54 close the coil 57 is de-energised and the plunger grips the tube 15 under the influence of the spring.

WHAT WE CLAIM IS:—

1. A haemodialysis machine comprising a blood pump, a dialyser and a bubble trap downstream of the dialyser and means for detecting air bubbles in the blood leaving the bubble trap in use via a translucent or transparent tube, said bubble detecting means comprising a lamp and a photocell on opposite sides of said tube so that the intensity of light falling on the photocell from the lamp is dependent upon the opacity of the contents of said tube between the lamp and the photocell, and a switching circuit

which has two states between which it is arranged to switch when the intensity of illumination of light received by the photocell deviates beyond a predetermined limit.

2. A machine as claimed in Claim 1 wherein said switching circuit includes a semi-conductor switching element.

3. A machine as claimed in Claim 1 or Claim 2 wherein said switching circuit includes a delay circuit which is operable in use to prevent the switching circuit from switching from said one state to said other state if a bubble below a predetermined size passes between the lamp and the photocell.

4. A machine as claimed in Claim 2 or Claim 3 wherein said switching circuit further includes a logic unit comprising at least one logic element; an output of said semi-conductor switching element being connected to an input of said logic element.

5. A machine as claimed in claim 4 wherein said logic element is an And gate.

6. A machine as claimed in Claim 4 or Claim 5 wherein a connection is furnished for providing a further input of said logic element with a voltage derived such that it is representative of the condition of said lamp.

7. A machine as claimed in any one of Claims 4—6 wherein an output of said logic unit to a further semi-conductor switching element which in use effects energisation and de-energisation of a relay coil.

8. A machine as claimed in any one of the preceding claims wherein said lamp and photocell are arranged in a housing which is clipped onto said tube.

9. A machine as claimed in Claim 8 when dependent upon Claim 7 wherein said relay coil has associated therewith a first set of contacts which when in use in a first relative position cause the production of a warning signal.

10. A machine as claimed in Claim 8 when dependent upon Claim 7 or as claimed in Claim 9 wherein said relay coil has associated therewith a second set of contacts which when in use in a first relative position cause a capacitor to discharge through a solenoid coil to thereby cause a plunger to grip said tube.

11. A haemodialysis machine as claimed in any preceding claim further including a saline drip for introducing a saline solution into the blood entering the blood pump, a further bubble detecting means being provided for detecting bubbles.

12. A haemodialysis machine substantially as herein described with reference to and as shown in the accompanying drawings.

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2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 1

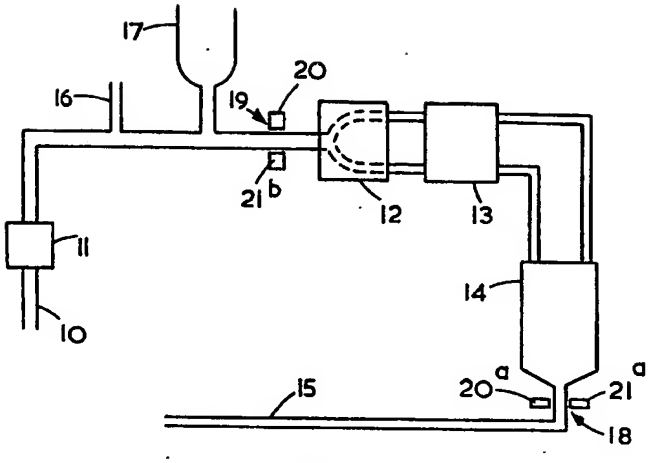

FIG. 1

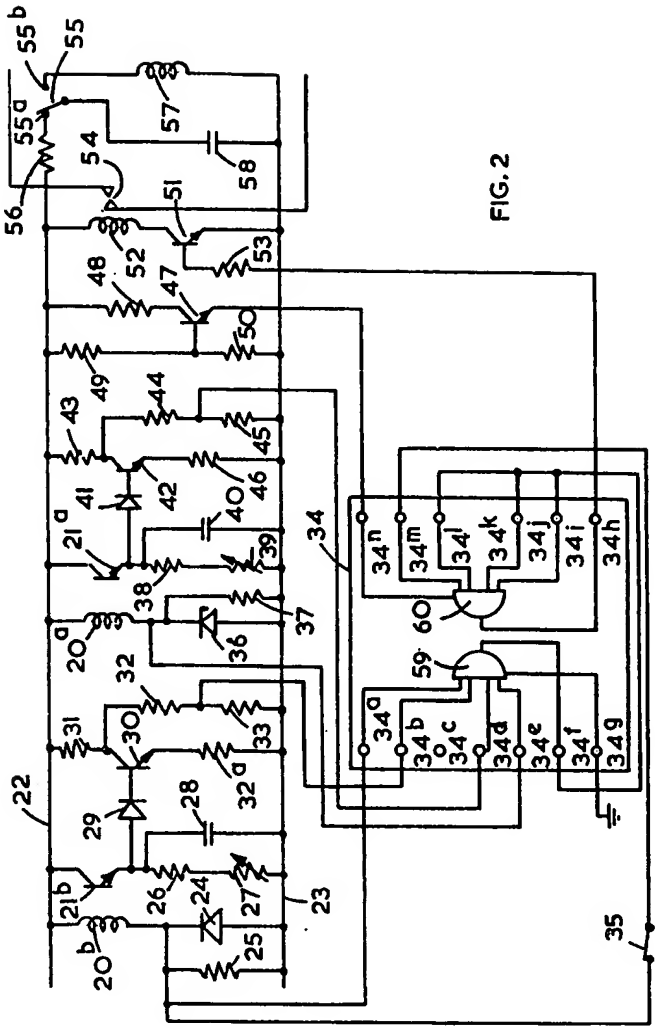
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FIG. 2